

**CLAIMS**

1. A process for the preparation of a polymer composite loaded with  
5 functioning matter wherein the process comprises contacting a polymer  
substrate and functioning matter with a plasticising fluid or mixture of  
plasticising fluids under plasticising conditions to plasticise and/or swell the  
polymer and incorporate the functioning matter, and releasing the plasticising  
fluid to obtain the polymer composite, wherein contacting is at a pressure in  
10 the range 1 to 1000 bar and a temperature in the range -200 to +500C, selected  
in manner that at least a proportion of functioning matter does not freeze or  
refreeze during processing, or if at a temperature at which freezing or  
refreezing may occur, that either matter is desiccated or a pressure constraint  
is applied whereby pressure is in a range having a maximum pressure less than  
15 1000 bar throughout contact of functioning matter and plasticising fluid,  
whereby at least a proportion of functioning matter retains its function in the  
polymer composite.

2. A process for the preparation of a polymer composite loaded with  
20 functioning matter wherein the process comprises contacting a polymer  
substrate and functioning matter with a plasticising fluid or mixture of  
plasticising fluids, in particular such as carbon dioxide or a mixture thereof,  
under plasticising conditions to plasticise and/or swell the polymer and  
incorporate the functioning matter, and releasing the plasticising fluid to  
25 obtain the polymer composite, wherein contacting is with cryopreserved or  
non cryopreserved functioning matter and is conducted at a temperature in a  
range at which functioning matter remains frozen or unfrozen, or thaws  
without refreezing during contacting, or is with cryopreserved or non  
cryopreserved functioning matter and is conducted at maximum pressure less  
30 than 1000 bar throughout contact of functioning matter and plasticising fluid,

whereby at least a proportion of functioning matter retains its function in the polymer composite.

3. A process as claimed in any of Claims 1 and 2 wherein functioning  
5 matter is non frozen or is physically preserved by cryopreservation, i.e. freezing, or is physically preserved by desiccating for example by contact with a desiccant.

4. A process as claimed in any of Claims 1 to 3 wherein at least 20% of  
10 functioning matter maintains function.

5. A process as claimed in any of Claims 1 to 4 wherein plasticising conditions comprise a pressure in the range 2 to 400 bar, more preferably 5 to 265 bar.

15

6. A process as claimed in any of Claims 1 to 5 wherein fluid is provided at plasticising conditions prior to contacting with polymer and functioning matter or is brought to plasticising conditions in contact with one or both of polymer and functioning matter.

20

7. A process as claimed in any of Claims 1 to 6 wherein the process is carried out for very short contact time of plasticising fluid and functioning matter of 2 milliseconds up to 10 minutes, or for longer contact time of plasticising fluid and functioning matter of 10 minutes to 2 hours.

25

8. A process as claimed in any of Claims 1 to 7 wherein the pressurisation period, whereby in the case of in situ or ex situ pressurisation the fluid is pressurised or is introduced to the functioning matter and polymer, is for a period of 1 second to 3 minutes.

30

9. A process as claimed in any of Claims 1 to 8 wherein the depressurisation period is rapid over a period of from 1 ms to 10 minutes; or is by prolonged gradual release of fluid over a period of in excess of 10 minutes up to 12 hours.

5

10. A process as claimed in any of Claims 1 to 9 wherein plasticising fluid includes carbon dioxide, di-nitrogen oxide, carbon disulphide, aliphatic C<sub>2-10</sub> hydrocarbons such as ethane, propane, butane, pentane, hexane, ethylene, and halogenated derivatives thereof such as for example carbon tetrafluoride or  
10 chloride and carbon monochloride trifluoride, and fluoroform or chloroform, C<sub>6-10</sub> aromatics such as benzene, toluene and xylene, C<sub>1-3</sub> alcohols such as methanol and ethanol, sulphur halides such as sulphur hexafluoride, ammonia, xenon, krypton, or a mixture thereof.

15 11. A process as claimed in any of Claims 1 to 10 wherein functioning matter is present in an amount with respect to polymer of  $1 \times 10^{-12}$  wt% to 99.9 wt%.

12. A process as claimed in any of Claims 1 to 11 wherein proliferative  
20 functioning matter is present in an amount with respect to polymer at a desired starting concentration allowing for survival and post processing growth.

13. A process as claimed in any of Claims 1 to 12 wherein functioning matter is selected from any subcellular, cellular or multicellular matter and  
25 aggregates and mixtures thereof including mammalian, plant and bacterial cells including (subcellular) organelles and aggregates thereof including pancreatic islet or liver spheroids and the like; non cellular matter such as liposomes.

14. A process for the preparation of a polymer composite comprising biofunctional material and loaded with functioning matter wherein the process comprises in a first stage contacting biofunctional material and polymer and a plasticising fluid or a mixture of plasticising fluids under plasticising conditions to plasticise and/or swell the polymer and incorporate the biofunctional material and subsequently introducing an amount of functioning matter and combining with polymer, and releasing the plasticising fluid to obtain the polymer composite, wherein contacting is at a pressure in the range 1 to 1000 bar and a temperature in the range  $-200$  to  $+500^{\circ}\text{C}$ , selected in manner that at least a proportion of functioning matter does not freeze or refreeze during processing, or if at a temperature at which freezing or refreezing may occur, that either matter is desiccated or a pressure constraint is applied whereby pressure is in a range having a maximum pressure less than 1000 bar throughout contact of functioning matter and plasticising fluid, whereby at least a proportion of functioning matter retains its function in the polymer composite.

15. Process as claimed in any of Claims 1 to 14 wherein polymer is selected from: polyesters including poly(lactic acid), poly(glycolic acid), copolymers of lactic and glycolic acid, copolymers of lactic and glycolic acid with poly(ethylene glycol), poly( $\epsilon$ -caprolactone), poly(3-hydroxybutyrate), poly(p-dioxanone), poly(propylene fumarate); poly (ortho esters); polyanhydrides; Poly(amino acids); polyacetals; polyketals; polyorthoesters; Polyphosphazenes; azo polymers; synthetic Non-biodegradable Polymers selected from: Vinyl polymers including polyethylene, poly(ethylene-co-vinyl acetate), polypropylene, poly(vinyl chloride), poly(vinyl acetate), poly(vinyl alcohol) and copolymers of vinyl alcohol and vinyl acetate, poly(acrylic acid) poly(methacrylic acid), polyacrylamides, polymethacrylamides, polyacrylates, Poly(ethylene glycol), Poly(dimethyl siloxane), Polyurethanes,

Polycarbonates, Polystyrene and derivatives; and Natural Polymers selected from carbohydrates, polypeptides and proteins.

16. A polymer composite comprising a polymer loaded with functioning  
5 matter according to the process as defined in any of Claims 1 to 15, wherein at least a proportion of functioning matter has retained function in the polymer composite.

17. A polymer composite as claimed in Claim 16 comprising polymer  
10 loaded with functioning matter which is non-established, ie which is loaded functioning matter, and is not proliferated, grown, adhered or otherwise modified post loading, at least a proportion of which has retained function in the polymer composite.

18. A polymer composite as claimed in Claim 16 or 17 which is in granular  
15 or monolith form.

19. A scaffold comprising a polymer composite loaded with functioning  
matter as claimed in any of Claims 16 to 18, optionally additionally  
20 comprising biofunctional materials, as hereinbefore defined, suitably sized and shaped for a desired application.

20. An apparatus for use in the preparation of a polymer composite or with  
use of the process as claimed in any of Claims 1 to 19, comprising one or  
25 more pressure vessels adapted for temperature and pressure elevation, means for depressurisation or for discharging of contents into a second pressure vessel at lower pressure, and means for introduction of functioning matter, dense phase fluid and polymer whilst the vessel is pressurised.

21. A polymer composite as claimed in any of Claims 16 to 1, a  
0scaffold thereof or the process for the preparation thereof as claimed in any  
of Claims 1 to 15 for use as a support or scaffold for drug delivery, for use in  
bioremediation, as a biocatalyst or biobarrier for human or animal or plant  
5 matter, for use as a structural component, for example comprising the polymer  
and optional additional synthetic or natural metal, plastic, carbon or glass fibre  
mesh, scrim, rod or like reinforcing for medical or surgical insertion, for  
insertion as a solid monolith into bone or tissue, as fillers or cements for wet  
insertion into bone or teeth or as solid aggregates or monoliths for orthopaedic  
10 implants such as pins, or dental implants such as crowns etc.

22. A process for preparing a polymer composite, a polymer composite, a  
scaffold, or the use thereof substantially as described in the description or  
illustrated in the Examples.